



News Alert – March 30, 2014

PSI Government Relations is providing the following legislative update to explain the structural challenges faced by the 340B drug discount program in helping patients to access and afford needed prescriptions. It is an overview of proposed actions being debated by lawmakers and regulators and not an endorsement of any particular reform.

Congress urges greater oversight and transparency for 340B drug discount program

The House Energy and Commerce Health subcommittee convened a long-awaited hearing last week to debate potential reforms to the Section 340B drug pricing program, the first review of the program in nearly ten years.

Created in 1992, the 340B program requires most drug manufacturers to provide nearly 11,000 participating safety-net providers with deep discounts (totaling about \$3.8 billion in 2013) for outpatient drugs used to treat low-income and uninsured patients. However, hospitals are not prevented from using the discounted drugs to also treat patients covered by Medicare or private insurance.

As a result, the Health Resources and Services Administration (HRSA) that administers 340B has been intensely criticized by lawmakers in recent years after government audits from 2011 reported that a lack of oversight and transparency is effectively allowing 340B providers to reap “windfall profits” on the higher reimbursement. They claim this is effectively converting 340B’s mission from serving vulnerable populations to creating a profit center for the provider. The Government Accountability Office (GAO) blamed this shift on the fact that 340B providers and manufacturers were essentially allowed to “police themselves and ensure their own compliance”, as well as the failure of HRSA to perform any of the audits authorized by Congress.

Critics have previously pointed to a recent study by researchers from the University of Chicago and Sloan Kettering Memorial Cancer Center documenting that those registered for the 340B program in 2004 or later served communities that were wealthier and have higher rates of health insurance. An earlier report produced by the pharmaceutical industry insisted that clinical decision-making by hospitals was being “skewed by efforts to take advantage of the 340B discount”.

Lawmakers cited other studies affirming this trend, including a white paper by Avalere Health revealing that two-thirds of 340B participating providers provide less charity care than the average United States hospitals, while charity care represents less than one percent of total costs for roughly 25 percent of 340B providers. They noted that such a nominal amount of charity care contrasts starkly with a dramatic rise in 340 drug purchases from \$1.1 billion in 1997 to more than \$7 billion by 2013.

Nearly all of the subcommittee members consequently urged HRSA to issue long-overdue rules and guidance that implement all of the recommendations of the Department of Health and Human Services Office of Inspector General (OIG) and GAO. This includes a “clear definition” of eligible patients and greater clarity regarding how covered entities spend program savings—both of which are lacking under the existing statute.

HRSA officials insisted that they have already made efforts to increase program oversight and integrity in response to the findings from OIG and GAO, but are limited in the scope of what they can do (especially in tracking how 340B revenue is used). They cited a recent court ruling invalidating HRSA rules requiring drugmakers to provide mandatory 340B discounts for orphan drugs when used for non-orphan indications—rulemaking that continues to face legal challenges brought by the Pharmaceutical Research and Manufacturers of America.



As a result, subcommittee members acknowledged that Congressional action was needed to expand HRSA's authority to increase oversight through rulemaking and guidance documents. This included a proposal by Rep. Gene Green (D-TX) to authorize HRSA oversight over orphan drugs.

Despite its current limitations, HRSA deputy administrator Diana Espinosa testified that the agency is moving forward with proposed rules later this year to detail how 340B ceiling prices should be calculated, civil monetary penalties imposed on non-compliant manufacturers, and administrative dispute resolution processes implemented. HRSA will also issue new guidance clarifying hospital eligibility requirements and the definition of a 340B patient.

Subcommittee chair Joe Pitts (R-PA) and Senator Charles Grassley (R-IA) are among the leading Republicans that have already asked the Medicare Payment Advisory Commission (MedPAC) for recommended changes, even though 340B falls outside of the commission's specific mandate. However, MedPAC decided at its March meeting to include only a discussion of current 340B issues in its June report to Congress and not make any specific recommendations.

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